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A comparison of inhalational induction of anaesthesia between incremental doses of sevoflurane and high dose sevoflurane in children under 2 years of age

Submission date
30/09/2005

Recruitment status
No longer recruiting

Registration date
30/09/2005

Overall study status
Completed

Last Edited
13/03/2014

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0265006729

Study information

Scientific Title

Study objectives
We intend to carry out a prospective, randomised trial comparing the use of incremental or high dose sevoflurane with O2/N2O for the induction of children under two years of age, to investigate this observed reaction to sevoflurane. We expect to see bradycardias only in the high dose group. Both methods are standard induction techniques.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Anaesthesia in elective surgery

Interventions
With parental consent, all children scheduled to undergo elective surgery who are to receive an inhalational induction will be eligible. Patients will be randomised to receive either incremental or high dose sevoflurane. The rate will be electronically recorded during induction of anaesthesia. Data will be subsequently analysed for alterations of heart rate: severe bradycardia being defined as a 20% reduction in heart rate from the baseline.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Sevoflurane

Primary outcome measure
Data will be subsequently analysed for alterations of heart rate: severe bradycardia being defined as a 20% reduction in heart rate from the baseline.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/01/2000

Completion date
01/01/2007

Eligibility

Key inclusion criteria
Children under two years of age with parental consent, all children scheduled to undergo elective surgery who are to receive an inhalational induction will be eligible.

Participant type(s)
Patient

Age group
Child

Upper age limit
2 Years

Sex
Both

Target number of participants
Not provided at time of registration

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
01/01/2000

Date of final enrolment
01/01/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Anaesthetics
Birmingham
United Kingdom
B15 2TH

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
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SW1A 2NL
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
University Hospital Birmingham NHS Trust (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration